REMARKS

Claims 1, 3-6, 8 and 9 are pending in the application and stand rejected. Reconsideration and withdrawal of the rejections is requested in view of the following remarks.

Rejection under 35 U.S.C §103

Claims 1, 3-6, 8 and 9 stand rejected under 35 U.S.C. 103(a) as being obvious over U.S. Pat. No. 4,849,141 ("'141 patent") to Fujioka et al. in view of the article "Collagen-biomaterial for drug delivery" by Friess ("Friess"). In particular, the Office Action states that the '141 patent discloses a method for preparing formulation comprising collagen, solvent and glucose wherein the formulation is cross-linked using UV irradiation or gamma irradiation. The Office Action acknowledges that the '141 patent does not teach sterilization by gamma irradiation, but finds that it does teach the desire to preserve and stabilize the formulation by adding preservatives and stabilizers.

The Office Action further states that Friess teaches gamma irradiation and thus opines that it would have been obvious to the skilled person to provide a formulation comprising collagen and glucose that is cross-linked by UV radiation as taught by the '141 patent and sterilized by gamma irradiation as disclosed by Friess, "motivated by the teaching of Friess that gamma radiation is the method of choice to sterilize collagen biomaterials mainly for its high efficacy and accurately controlled dose, with reasonable expectation of having formulation comprising collagen and glucose that is cross-linked with UV radiation and subsequently sterilized efficiently and accurately by gamma irradiation wherein the formulation is stable at storage and sterile when ready to use." Applicants are in respectful disagreement with the Office Action.

Erstwhile, Applicants respectfully traverse. In order "[t]o establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." MPEP §2142. The Office Action has made no indication whatsoever of where in Friess or in the '141 patent the skilled person would find the urging to combine the two references as asserted by the Office Action. The Office Action's proffered motivation is nothing more than a mere statement of the benefit conferred by the invention and does not set forth the required showing of motivation but rather merely applies the benefit of hindsight in combining disjointed references with the benefit of the invention itself as an explicit roadmap.

The '141 patent teaches a method for preparing a molding material for use in making sustained released formulation. The '141 patent specifically teaches that such a formulation "must be uniform" but that where the "molding material consists of collagen...the molding material cannot exist in the form of a uniform and homogenous solution." [See '141 patent at column 1, lines 32-41]. In contrast, the present invention teaches a composition having collagen and sugar material which has been exposed to UV radiation, gamma radiation or both. Such treatment can result in collagen fragmentation; i.e. a formulation that are no necessarily uniform. As such the '141 patent clearly and specifically teaches away from the use of UV radiation or gamma radiation where the exposure to the UV and/or gamma radiation may lead to fragmentation of the collagen molecules.

The Office Action's reliance on Friess' assertion that gamma irradiation is "a method of choice to sterilize collagen biomaterials mainly for its high efficacy and accurately controlled dose" is out of context and ignores other highly relevant statements from the same paragraph. In fact, Friess merely includes gamma radiation as one sterilization method and specifically acknowledges that "[s]tudies on the effect of γ-irradiation on collagen structure clearly indicate chain scission resulting in a fraction of lower molecular weight material" and that "[t]hese molecular changes due to γ-sterilization reduce the mechanical strength of collagen." (page 121, paragraph 3.5.2) Thus, Friess also teaches away from using γ-irradiation on collagen where the strength of the composition is of importance. Furthermore, there is no mention of glucose in combination with collagen anywhere in Friess, and thus no reason for the skilled person to expect that γ-irradiation on such a compound would provide desirable results. Thus, the skilled person would not in fact have a "reasonable expectation of having formulation comprising collagen and glucose that is cross-linked with UV radiation and subsequently sterilized efficiently and accurately by gamma irradiation" to yield desirable results.

In view of the foregoing, it is submitted that the claims are in condition for allowance. A Notice of Allowance is requested.

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